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not to forget the values and principles that tie us together and define who we are.

Ethical PPE: Overseeing Research in the Time of COVID-19

Edward De Vos

As many in a weary nation look toward science for insights, answers, and a path out of this modern plague, science itself runs the risk of exposure and illness. Since the end of World War II, the *Nuremberg Code* (1947), the *Declaration of Geneva* (1948), the *Helsinki Declaration* (1964), the *Belmont Report* (1978) and its codification in the *Common Rule* in the U.S. Code of Federal Regulations represent serious efforts to protect participants in human subjects research from risks associated with their participation.

In research settings, whether university-, hospital-, or industry-based, it is the Institutional Review Board (IRB) or Human Subjects Committee that is charged with overseeing an institution's human protections program and compliance with regulations. This includes assuring that key research personnel have successfully completed training programs on protecting human subjects from research risks, reviewing research protocols in accordance with federal regulations and criteria, providing feedback and approvals to researchers before implementing protocols, overseeing the proper execution of the research, responding to requests for amendments prior to their implementation, and investigating unanticipated problems and adverse events that may occur despite the best of intentions.

Research is difficult, both theoretically and practically. While the practice of ethical research is grounded in legal regulations, the ethics themselves are rooted in normative values and a more universal moral imperative. Translating this code into practical operations can be a tricky affair. Some very challenging protocols require what verges on

Solomonic wisdom to render a decision. Thankfully, most protocols are not that challenging. And many, historically, have carried no more than minimal risk, often defined as the risk associated with day-to-day life.

Yet as COVID-19 captures headlines and the media report daily new case counts and deaths with the fervor of sports fans following their playoff-bound team or investors following the stock market, the risks associated with daily life have changed radically. COVID-19 is not only an important subject of study, but it has affected the context within which research is conducted, and the risk environment within which IRBs must deliberate.

It is within this broader context that I received NIB's survey on COVID-19 and its impact on IRBs. The survey provided an opportunity to reflect and sort out some of the challenges I experienced as an IRB Chairperson, and the efforts we undertook to address them. This personal story shares some of those challenges and what we've learned thus far as well as some emerging dilemmas as the pandemic continues.

The first challenge is a logistical challenge associated with review and oversight of COVID-19 research. This is less a matter of "COVID-19 Research," per se, but accommodations to previously approved protocols that involved face-to-face interviews. These were protocols that were approved before we were even aware of COVID-19 and prior to widespread mitigation efforts, at the state level or nationally. I reached out to all Principal Investigators (PIs) of active protocols requiring amendments if they were still actively engaged in recruitment and/or interviewing. I created a streamlined application process that outlined the required changes (to informed consent, recruitment materials, and the addition of screening questions to online interview protocols), and requested current information on the status of recruitment, interviews completed, and interviews still to be conducted. This resulted in a spike of amendments to be processed, but the streamlined procedures facilitated administration.

The next challenge involved ethical, regulatory, or institutional policy challenges or concerns.

Online interviewing carries additional risks and responsibilities. *Both* the researcher as well as the participant must be able to identify spaces to conduct the interview in which they are unlikely to be observed, overheard or interrupted. Except for those living alone or those with privileged amounts of space, this can pose a challenge. Nevertheless, for much behavioral research, where a breach of confidentiality may be the greatest risk attached to participation, the need to maintain privacy is critically important. In addition to modifying the informed consent documents to stipulate that privacy, the interview protocols must add screening questions regarding the physical setup within which the e-interview will be conducted. This begs a separate question about cybersecurity and the privacy afforded by varying e-platforms. This remains a concern.

Among the *Belmont Report's* three fundamental ethical principles is *Justice*, which concerns the equitable distribution of risks and benefits among participants. While researchers may seek to broaden their pool of participants to gain greater diversity and potential generalizability (and, should the results warrant, utility), the demands of online research may pose challenges to inclusion of more diverse populations. Historically underserved and marginalized populations are disproportionately represented among the poor, and poverty may limit the ability of some to participate in online research. Internet access, bandwidth, and equipment capacity may pose obstacles.

Previously, I described the extra efforts needed to secure confidentiality to minimize risks in accordance with the *Belmont Report's* principle of *Beneficence*. Here too, however, poverty, through its effects on affordable housing and population density, may make it difficult for would be participants to secure the space and privacy required for confidential online interviews as stipulated by the informed consent as required by the approved protocol.

As the COVID-19 pandemic continues, we must weigh the need for temporary accommodations versus long term sustainable solutions. If in the short term we assign higher priority to minimizing risk, we risk paying less attention to equitable

distribution of burden and benefit. As the pandemic continues, we must seek alternative ways to counteract the disproportionate medical and economic impact the disease has on the poor and people of color, and to identify feasible ways to promote and secure their involvement in research. Without those efforts, we run the risk of turning back the clock on research's effort to diversify the knowledgebase, and with it, secure benefits for all segments of the population.

Finally, I offer general advice to IRBs and researchers during this pandemic, whether they are directly studying COVID-19 or not. While physical contact, viral spread, illness and death must be the top priorities, I urge IRBs not to overlook the implications of moving to electronic platforms for conducting other forms of research. In most instances, the researcher will be unable to control their participant's environment. As such, increased attention must be given to maintaining the confidentiality of the interview through informed consent attestations, and through the addition of screening questions within the interview protocol itself. Longer term, attention must be given to alternative models to secure more diverse participation, which will secure added benefits for those who have historically borne disproportionate risk for so long.

Navigating the Ethics of a Crisis

Jennifer Randles

I vividly recall Friday, March 13th, 2020. It was an unseasonably warm, sunny day in Central California, and though I did not know it at the time, my last working day on campus for the foreseeable future. I attended several meetings that day related to my various roles—study principal investigator, faculty, Sociology Department Chair, and Chair of our University IRB, the Committee for the Protection of Human Subjects. Just two days earlier, I held my final in-person class meetings